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Pesticide Fact Sheets-2,4-DB (No. 179)

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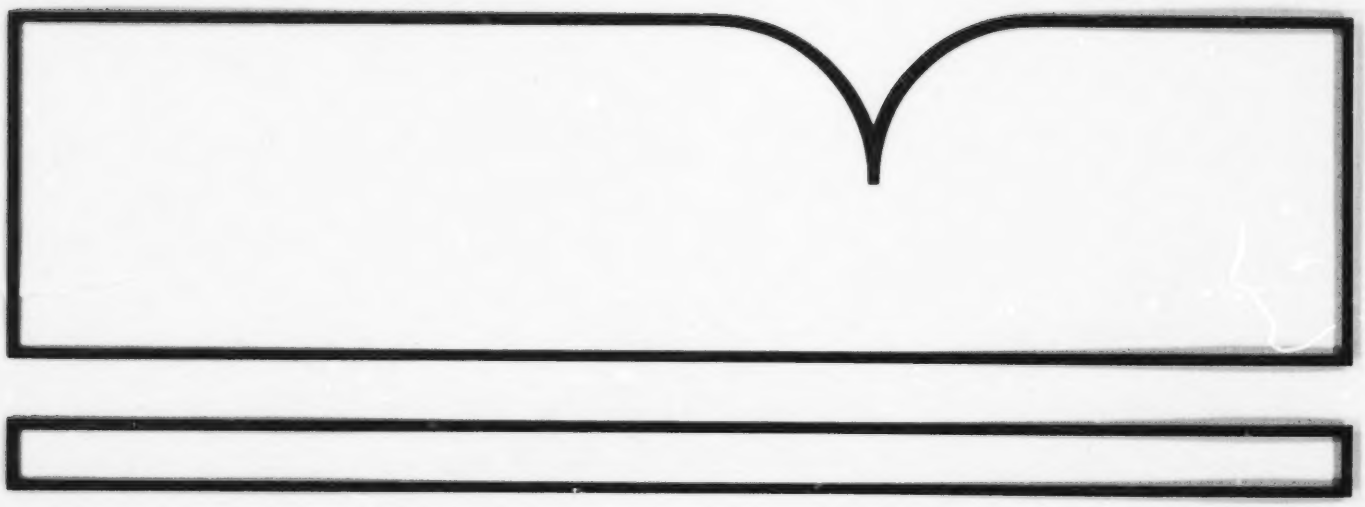

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16. Abstract (Limit: 200 words)

This document contains up-to-date chemical information, including a summary of the Agency's regulatory position and rationale, on a specific pesticide or group of pesticides. A Fact Sheet is issued after one of the the following actions has occurred.

1. Issuance or reissuance of a registration standard,
2. Issuance of each special review document,
3. Registration of a significantly changed use pattern,
4. Registration of a new chemical, or
5. An immediate need for information to resolve controversial issues relating to a specific chemical or use pattern.

17. Document Analysis a. Descriptors

Pesticides, regulations, Chemical Information Fact Sheet, Use Patterns, science findings.

b. Identifiers/Open-Ended Terms

c. COSATI Field/Group

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Washington, DC 20460

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EPA

Pesticide Fact Sheet

Name of Chemical: 2,4-DB (See Below)
Reason for Issuance: Registration Standard
Date Issued: OCT 03 1988
Fact Sheet Number: 179

1. Description of Chemical(s)

Generic Name(s): 4-(2,4-dichlorophenoxy)butyric acid (2,4-DB); 2,4-DB sodium salt; 2,4-DB, dimethylamine salt; 2,4-DB, butyl ester; 2,4-DB, 2-butoxyethyl ester; and 2,4-DB, isooctyl ester.
Common Name(s): 2,4-DB, and its sodium salt, amine and esters.
Trade Name(s): 2,4-DB is available under the trade names, Butoxone and Butyrac, formulated as an amine salt or ester.
EPA Shaughnessy Codes: 030801 (acid)
030804 (sodium salt)
030819 (dimethylamine salt)
030853 (2-butoxyethyl ester)
030856 (butyl ester)
030863 (isooctyl ester)
Chemical Abstracts Service (CAS) Number(s): 94-82-6 (acid)
10433-59-7 (sodium salt)
2755-42-1 (dimethylamine salt)
32357-46-3 (2-butoxyethyl ester)
6753-24-8 (butyl ester)
1320-15-6 (isooctyl ester)
Year of Initial Registration: 1958
Pesticide Type: Herbicide; plant growth regulator
Chemical Family: Chlorinated phenoxys
U.S. and Foreign Producers: 2,4-DB technical products are manufactured by both U.S. and foreign companies.

2. Use Patterns and Formulations

Registered Uses: Terrestrial Food

Predominant Uses: Agricultural crops, alfalfa (16-67% of total usage), soybeans (27-68%), peanuts (5-13%), and clover (less than 2%).

Pests Controlled: Broadleaf weeds

Formulation Types Registered: Liquid (emusifable concentrate, soluble concentrate)

Method of Application: Ground equipment and aircraft.

3. Science Findings

Existing data are inadequate to assess the carcinogenic potential of 2,4-DB. In a rat study, 2,4-DB was not oncogenic. In a mouse oncogenic study there was a weak but possible dose-relationship involving hepatocellular carcinomas in males. A new study or historical control data in certain tumor incidences in the strain of mice at the testing facility are required before the significance can be determined. Additional data are needed to determine the teratogenic potential of 2,4-DB.

2,4-DB is generally formulated as a sodium salt, an amine salt or an ester. The amine and ester forms may differ in biological activity and environmental fate from the parent compound. Data are needed on each amine and ester to enable a complete assessment.

Concern about possible groundwater contamination exists for the family of 2,4-D compounds (2,4-D, 2,4-DB, and 2,4-DP). Additional data and a label warning statement are required.

Chemical Characteristics: (2,4-DB acid technical)

Physical State: Crystalline solid
Color: White to light brown
Odor: Slight phenolic
Melting Point: 116 to 119 °C
Solubility: Highly soluble in acetone, benzene, carbon tetrachloride, diesel oil and kerosene; slightly soluble in water.
Vapor Pressure: Negligible at 25 °C
Stability: Stable

Toxicological Characteristics: (Note: 2,4-DP acid is test material.)

Acute Oral Toxicity - Rats: 2.33 g/kg (males), 1.54 g/kg (females), 1.96 g/kg (males), 1.47 g/kg (females); Toxicity Category III

Acute Dermal Toxicity - Rabbits: > 2 g/kg; Toxicity Category III

Primary Eye Irritation - Rabbits: All irritation cleared at 7 days; Toxicity Category III

Primary Skin Irritation - Rabbit: No irritation at 27 and 72 hours; Toxicity Category IV

Subchronic Toxicity - Dog:
Lowest-observed-effect level (LOEL) = 25 mg/kg/day
No-observed-effect level (NOEL) = 8 mg/kg/day
Mortality, body weight depression, histolopathological findings at LOEL and highest dose level (80 mg/kg/day)

Chronic Toxicity:

Chronic Feeding/Oncogenicity - Rats:
Systemic LOEL = 30 mg/kg/day for non-oncogenic effects
Systemic NOEL = 3 mg/kg/day for non-oncogenic effects
Decreased mean body weight gains, change in blood chemistry and hematology parameters and significantly lower heart weights than control. Not oncogenic under the conditions of the study.

Oncogenicity Study - Mice:
Weak, but possible dose-relationship involving hepatocellular carcinomas in males. A new study is required or this study may be upgraded if historical control data on certain tumor incidences in the strain of mice at testing facility are submitted and justification that female mice of this strain were tested at or close to the Maximum Tolerated Dose (MTD).

Teratology Study: No acceptable data available.

Reproduction Study:
NOEL = 15 mg/kg/day
At highest dose (75 mg/kg/day) ovarian weight was significantly less in dams mean body weights were lower, fewer pups were born per litter, and extremely high pup mortality occurred during lactation period.

Mutagenicity Study:
Ames study negative with and without metabolic activation.
Chinese Hamster Ovary assay with activation suggests a weak mutagen immediately below doses causing high levels of cytotoxicity.
In Chinese Hamster Ovary assay a significant increase in chromosomal aberration with 17.25-hour exposure, but no increase with 2-hour exposure. Unscheduled DNA synthesis, no evidence of induction.

Physiological and Behavioral Characteristics:

Mechanism of Pesticide Action: Phenoxy herbicides (including 2,4-DB) are hormone weed killers affecting the activity of enzymes, respiration, and cell division.

Environmental Characteristics: No data are available.

Ecological Characteristics: (Note: all figures are LC_{50} values)

Avian Toxicity: No acute oral studies available. Dietary studies indicate 2,4-DB acid is practically nontoxic (> 5000 ppm, respectively) to waterfowl and upland game birds.

Aquatic Organism Toxicity: 2,4-DB acid is moderately to slightly toxic to freshwater fish (18 ppm fathead minnow, 7.5 to 17 ppm bluegill sunfish, 2.0 to 14 ppm rainbow trout). No studies are available for freshwater invertebrates.

Nontarget Insect Toxicity: 2,4-DB dimethylamine salt has a low toxicity to bees.

Nontarget Plants/Endangered Species: Since 2,4-DB is a broadleaf herbicide, a potential hazard exists for nontarget plants. Hazard assessments for endangered species cannot be completed until additional data are received.

Tolerance Assessment:

Tolerance Established: Tolerances of 0.2 ppm have been established for 2,4-DB and its metabolite 2,4-D in or on alfalfa, clover, mint hay, peanuts, soybeans, soybean hay, and birdsfoot trefoil (40 CFR 180.331).

Results of Tolerance Assessment: A provisional acceptable daily intake of 0.01 mg/kg/day for 2,4-DB acid has been established based on a rat chronic feeding study with NOEL of 3 mg/kg/day and utilizing a 300X safety factor. A Theoretical Maximum Residue Contribution (TMRC) for the U.S. population was calculated to be 0.000083 mg/kg/day which utilizes 0.83 % of the PADI

Reported Pesticide Incidents: Based on the Pesticide Incident Monitoring System files covering the period of 1966 to 1979, reports were received concerning off-target movement for unspecified 2,4-D (family) compounds. The incidents involved drift from aerial (173 reports) and ground (104 reports) applications, as well as volatilization (35 reports) and resulted in damage to nontarget crops and other desirable plants.

4. Summary of Regulatory Position and Rationale

Summary of Agency Position: The Agency has concluded that existing data are inadequate to assess the carcinogenic potential of 2,4-DB. Under conditions of the study 2,4-DB was not oncogenic in the rat. In a mouse oncogenic study with 2,4-DB acid there was no conclusive evidence of oncogenicity. However, there was a weak but possible dose relationship involving hepatocelluar carcinomas in males. This mouse oncogenicity was deficient because historical control data on certain tumor incidences in the strain of mice at the testing facility were not submitted. Unless the data are submitted, the study must be repeated.

Data are being required on the salt, ester and amine formulations of 2,4-DB as well as on the acid. The Agency will not establish any significant new food use tolerances or register any significant new uses at this time.

Unique Label Warning Statements: Groundwater Advisory - (end-use products [EPs]): "This product can reach ground water as a result of mixing and loading. To minimize groundwater contamination from spills during mixing and loading and cleaning of equipment, take the following steps:

Mixing and Loading: When mixing, loading or applying this product, wear chemical resistant gloves. Wash nondisposable gloves thoroughly with soap and water before removing.

The mixing and loading of spray mixtures into the spray equipment must be carried out on an impervious pad (i.e., concrete slab, plastic sheeting) large enough to catch any spilled material. If spills occur, contain the spill by using absorbent material (e.g, sand, earth or synthetic absorbent). Dispose of the contaminated absorbent materrial by placing in a plastic bag and following disposal instructions on this label.

Triple rinse empty containers and add the rinsate to the mixing tank.

Cleaning of Equipment: When cleaning equipment, do not pour the washwater on the ground; spray or drain over a large area away from wells and other water sources."

5. Summary of Major Data Gaps

The following data are required for 2,4-DB acid. The Agency is also requiring data on each individual salt, ester and amine of 2,4-DB. Specific requirements are detailed in the Data Tables, Appendix I of the Registration Standard, which can be obtained from the Product Manager listed below.

Study	Due Date - From Date of Standard
Product Chemistry	6 - 15 months
Residue Chemistry: Plant and animal metabolism Analytical methods Residue studies	18 - 24 months
Toxicology: Acutes, subchronic oral, 21-day dermal, second species oncogenicity or historical data from mouse oncogenicity study, chronic feeding (nonrodent) teratogenicity, mutagencity	6 - 50 months

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Ecological Effects: Avian oral/dietary, aquatic organisms (freshwater fish/ invertebrates), nontarget insect and plant studies	9 - 12 months
Environmental Fate: All studies	9 - 27 months

6. Contact person at EPA

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